

PATENT / DOCKET NO. 10287.39
Customer No.: 000027683

III. Remarks

A. Status of the Application

Claims 8-11 and 35-37 are pending.

B. Rejections of Claims 8-11 and 35-37 under 35 U.S.C. §112, First Paragraph

Office Action

Claims 8-11 and 35-37 were rejected for introduction of new matter. In particular, Claims 35-37 were rejected for the following: "where target receptors have a length of up to 1mm," "a labeled complex having a predetermined molar ratio of the labeled substances," and "number and length of target receptors."

Claim 35 was rejected for "where single-stranded target receptors have a predetermined base sequence."

Response

Support for the objectionable claim language is found in the specification and originally filed claims as follows:

"Where target receptors have a length of up to 1mm:" At page 9 and in Claim 3 as originally filed, the target receptor is cited as formed in a slender shape (page 9, line 3). The size of the "slender shape" is not expressly defined (page 9, line 5), however, for example, the form is as long as or sufficiently longer than the particle size (page 9, lines 7-8), for example, about 10 times as long as the particle size, for example, about 10 μ m (page 9, lines 8-9). At page 5, the particle size is cited as preferably of the order of about 0.1 μ m ~ about 1 mm (lines 11-13). Therefore, the target receptor may be from 0.1 μ m to about 10 mm. The Office Action of Feb. 12, 2003 requested that a limit be put on the length of immobilized polynucleotides. Since the value of 1 mm is expressly stated in the specification, that value was selected as a limit on the length of target receptors.

"Where single-stranded target receptors have a predetermined base sequence:" Support is found in Claim 10 as originally filed as follows:

A labeled complex according to claim 9, wherein said carrier is coated with one of a pair of chemical compounds that are specifically bonded, such as avidin, biotin and the like, said target receptor is a DNA fragment having a predetermined base sequence, the other chemical compound of said chemical compound pair is bonded at one position, and said fluorescent substance is bonded at an other position.

Claim 10 as originally filed is indirectly dependent upon Claim 7 as originally filed which states that the target receptor is a single strand nucleic acid. Further, lines 12-13 of page 11 state that the target receptor is a single strand nucleic acid. That the receptor may be single stranded has further support in Fig. 7 (a) –

PATENT / DOCKET NO. 10287.39

Customer No.: 000027683

7(f) where target receptors of the two types of labeled composite particles 40, 41 are denatured by an alkaline solution to be a single strand (page 34, lines 12-14). Fig. 7(d) and Fig. 7(e) demonstrate a labeled complex wherein the target receptor is single stranded.

"A labeled complex having a predetermined molar ratio of the labeled substances:" Support is found at page 5, lines 5-6 as follows: "The target receptor holds or can hold one or two or more types of targets, and in all of the labeled substances, predetermined types are contained at predetermined molar ratios," and at page 24, lines 14-18 as follows: "The labeled composite particle 10, as shown in FIG. 1(a), has: a magnetic particle 11, being a micro particle that is one carrier; fluorescent substances 13 (O) and 15 (Δ), being labeled substances in which predetermined types (two types for simplicity of description) are contained at predetermined molar ratios to the whole."

"Number and length of target receptors:" The Office Action states that support is present for the number and spacing of labeled substances on a receptor. Support for the target receptor formed in a "slender shape" such as a line, a thread, a hair, a stick and the like is present at page 9, lines 1-4. Support for the slender shape of the receptor and the function of the slender shape of the target receptor is found at page 9, lines 10-17 as follows:

The reason why a slender shape is formed is to make it play a role as a spacer where, by attaching a labeled substance such as a luminescent material and the like on one end, compared with the case of attaching the labeled substance to a carrier such as a micro particle and the like, the space to the carrier and the space and distance between the labeled substances are expanded, and hence energy movement between the labeled substances and the occurrence of quenching are prevented, so that it guarantees more reliably the possibility of consistent discrimination of emissions and the like.

In this sentence, Applicants are comparing the situation where a labeled substance is attached to a carrier and the situation where the labeled substance is attached at a distance from the carrier. That distance or space is provided by the length of the target receptor.

Further support for the length of the receptor is found at page 10, lines 14-16 where not only whole DNA and RNA, but also the case of fragments of DNA and RNA is included. Whole DNA and RNA would have a different length than fragments of DNA and RNA. Further, the sentences at lines 22-25 state that it is preferable that the location at which the labeled substance is bonded and the location at which the carrier is bonded are as far apart as possible. Preferably the locations correspond to one end and the other end of the double strand.

PATENT / DOCKET NO. 10287.39
Customer No.: 000027683

Applicants believe that written description support for the claim language in the cited independent claims is present as set forth above and that, therefore, the claim language of the dependent claims also has written description support. Applicants respectfully request that the rejection of Claims 8-11 and 35-37 under 35 U.S.C. §112, first paragraph, be withdrawn for the reasons cited herein.

C. Conclusion

It is believed that all matters set forth in the Office Action have been addressed. Reconsideration and an early indication of the allowability of the pending claims are respectfully requested. Should the Examiner believe that an interview with Applicant's undersigned agent would expedite consideration of the pending claims, the Examiner is invited to call the undersigned agent at 512.867.8528.

Respectfully submitted,

Gloria L. Norberg

Gloria L. Norberg
Registration No. 36,706

Dated: December 29, 2003
HAYNES AND BOONE, LLP
901 Main Street - Suite 3100
Dallas, Texas 75202-3789
Telephone: (512) 867-8400
Facsimile: (214) 200-0853
ipdocketing@haynesboone.com

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below:	
Fax Number: (703) 872-9306	
<u>NISHI PASADYA</u>	
TYPE OR PRINT NAME	
<u>[Signature]</u>	
SIGNATURE	
<u>12/29/03</u>	
DATE OF TRANSMISSION	